D1365B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

January 23, 1998

WARNING LETTER
CHI-10-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert W. Sessions, President
Ferris Manufacturing Corp.
300 W. 83rd St
Burr Ridge, IL 60521

Dear Mr. Sessions:

During the inspection of your firm from July 24 to September 26, 1997, Investigator Norman L. Brown determined your firm manufactures Polymem Membrane, Polymem Polywic, and Polymem Alginate wound dressings. Wound dressings are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Polymem dressing is misbranded within the meaning of Section 502(a) of the Act, in that its labeling contains statements which represent or suggest that the device is adequate and effective for use because it contains wound healing agents and a mild bacteriostatic agent. These representations are false or misleading or otherwise contrary to fact because the device is not adequate or effective for such purposes.

Additionally, product labeling for Polymem Membrane dressing contains the following claims, which would further misbrand the product.

1. "Smart dressing designed to resist bacteria and help build new skin tissue."

2. "helps prevent hematoma and contributes to rapid wound healing"

3. "minimize swelling and control pain"

4. "increases oxygen tension at the incision site"

5. "control bacteria"

6. "minimizes scarring"

7. "No other dressing has ever been proven to heal faster than PolyMem."

8. "The superabsorbent polymer contained in PolyMem draws wound fluid, natural growth factors, and nutrients to the wound site."

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Stephen D. Eich, Compliance Officer.

Sincerely,

/S/

Raymond V. Mlecko
District Director